



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/869,700 09/04/01 HENRY

R 03000018AA

MC GUIRE WOODS

HM22/1107

1750 TYSONS BOULEVARD SUITE 1800
TYSON'S CORNER

MCLEAN VA 22102-4215

EXAMINER

REAMER, J

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

11/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/869,700

Applicant(s)

HENRY, RICHARD

Examiner

James H. Reamer

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 to 13, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higson et al or Sethia. Both of the references teach the treatment of the bladder by introducing lignocaine in a solution along with sodium bicarbonate through a urethral catheter into the bladder. This procedure renders claims 1 and 3 to 8 obvious. Claim 2 recited the addition of the local anesthetic and alkalinizing agent separately to the bladder and claims 15 and 16 recite the specific concentrations for each of the separate solutions. No patentability can be seen in the separate addition of the two ingredients versus the combined addition of the ingredients as taught by the two references since the final solution in the bladder is the same. The specific concentrations recited in claims 15 and 16 are also not considered to be patentable absent evidence that the concentrations produce unexpected results. The compositions claimed in claims 9 to 13 are likewise considered to be obvious since the composition in a single-use syringe is considered to be an obvious means to administer the otherwise known composition.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Higson et al or Sethia in combination with Askin. See above for the teachings of the two primary

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references. Askin teaches that the use of a local anesthetic to treat interstitial cystitis is known. The two primary references teach that the optimal anesthetic effect can be achieved at an alkaline pH. It would therefore be obvious from these teachings to add an alkalinizing agent to the treatment procedure of Askin to improve the effectiveness of the treatment. The combination renders the instant process obvious absent evidence of unexpected results.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The references are cited to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Reamer whose telephone number is (703) 308-4461. The examiner can normally be reached on 5:30 AM to 2:00 PM Monday-Friday.

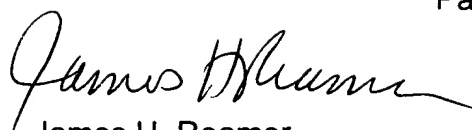
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-3909.

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A handwritten signature in cursive script, appearing to read "James H. Reamer".

James H. Reamer
Primary Examiner
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JHR

November 6, 2001